REMARKS

In the present Amendment, Claim 77 has been amended to incorporate the subject matter of Claim 78. Claim 89 has been amended to incorporate the subject matters of claims 64 and 65. Accordingly, Claims 64, 65 and 78 have been cancelled. Claims 66-69 and 79-82 have been amended to correct their dependency. No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, Claims 60-63, 66-69, 73-77, 79-83 and 85-90 will be pending.

At page 2 of the Action, Claims 60-69, 73-83 and 85-90 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Porssa et al (U.S. 6,251,964) in view of both WO-A-98/15575 ("WO '575") and Sahatjian et al (U.S. 5,674,192).

Applicants submit that this rejection should be withdrawn because Porssa et al, WO '575 and Sahatjian et al do not disclose or render obvious the present invention, either alone or in combination.

Independent Claims 77 and 89 have been amended to define the nature of the crosslinking. Crosslinking is achieved by incorporation of the crosslinkable monomer as defined, and the step of carrying out the crosslinking (in step a iii).

The Examiner has rejected both Claims 77 and 89, as well as 78 and 65, as being obvious over Porssa et al in view of WO '575 and Sahatjian et al. The Examiner has particularly pointed to the disclosure of drug delivery in Porssa et al at column 6, line 63. However, this passage relates to a different crosslinked polymer to that defined in the present claims. It is noted from column 6, line 49, that there is a mutual crosslinking of the mucopolysaccharide and the zwitterionic terpolymer by electrostatic crosslinking. There is no suggestion to crosslink

covalently, using a monomer having a crosslinkable group. Nor, in the passage from column 6, line 49 to 65, is there any suggestion to use the ionically crosslinked gel as a coating on a substrate.

There is no disclosure in Porssa et al, apart from the passage identified by the Examiner, of using the polymers described therein in combination with any pharmaceutical active other than the anionically charged mucopolysaccharides. Those actives, on the other hand, are described extensively therein. There is no disclosure of using the polymer for delivery of other specific drug types. There is therefore no motivation on the person skilled in the art, from Porssa et al itself, to use the polymers in conjunction with therapeutic actives other than the anionic mucopolysaccharides. Further, there is no motivation to consider that the polymers described therein would have utility for nucleic acids or proteins. Furthermore it is clear from Porssa et al that the anionic mucopolysaccharides have activity in the circulation. The polymers, and implants coated with the polymers, are described as having useful applications to remove anticoagulant (anionic mucopolysaccharides) from the system, or alternatively to deliver such actives to the circulation over an extended period of time (column 7, lines 30-35).

There is no suggestion that the polymers described in Porssa et al can be used to coat an implant which would be useful for delivering actives to a target in the body other than to the circulation.

WO '575 discloses a nucleic acid which has as its target smooth muscle cells. Thus although the nucleic acid may be delivered into a blood vessel, the target is not the circulation itself, nor blood specifically, but is the smooth muscle cell at the site of an injured blood vessel that perfuses such smooth muscle cells. One way of delivering the nucleic acid active is to deliver this to a coating of polymer coated on a balloon catheter impregnated with the nucleic

acid (page 19, line 26 to page 20, line 6). The balloon is inflated in the region of the arteriosclerosis, i.e. where the damaged smooth muscle cell is located. Any delivery to the circulation will mean lower levels of delivery to the target cells. A balloon catheter is not an implant as defined in the present claims 77 and 89. Rather it is a temporary device which is positioned in the respective site during an angioplasty operation and removed at the end of such operation.

It would not have been obvious to a person skilled in the art to consider the actives of WO '575, as replacements for the heparin and other anionic mucopolysaccharides used in Porssa et al. WO '575 does not describe delivery of actives from implants. The target for the anionic mucopolysaccharides active in Porssa et al is the circulation itself, because of the activity of the actives on blood itself. The target of the actives described in WO '575 is different, namely smooth muscle cells, usually adjacent to blood vessels. If the active of WO '575 was to be delivered in the same reservoir system proposed in Porssa et al, the active would not be delivered to the tissue adjacent to the implant but would instead be delivered into the circulation and taken away from the smooth muscle cells.

It is to be noted that there is no suggestion in either WO '575 or Porssa et al of any relationship between the nucleic acids and anionic mucopolysaccharides, on their target tissues, nor indeed on their mode of delivery. It would therefore not have been obvious to interchange the actives, but rather such substitution would be contraindicated for the reasons given above.

With regard to Sahatjian et al, again the objective is delivery of active ingredients directly to the wall of a blood vessel, this tissue being the target for the respective active (column 3, line 64 to column 4, line 6). As indicated at column 4, lines 5-6, it is important that the active is not "washed away by body fluids," that is, by blood. Thus the drug in Sahatjian et al is to be

delivered in a totally different location to the proposal in Porssa et al that drug be delivered specifically into the circulation. This target for the drug is emphasized also in the passage describing delivery from a gel coated onto a stent (i.e., an implant) (column 10, lines 49-51 and 58-63). The objective is to deliver the drug to tissue adjacent to the location in the blood vessel where the stent is positioned.

It is to be noted further that the polymer coatings in Sahatjian et al, mentioned at column 3, lines 1-6, or at column 3, lines 56-62, are all nonionic or anionic. Specific examples of anionic polymers are given at column 7, line 43 to column 8, line 2. The hydrogels are covalently crosslinked, although a crosslinking system distinct from that now defined in Claims 77 and 89 is required, involving exogenous crosslinker, in this case polyisocyanate or dlisocyanate (column 7, lines 39-40 and Example 1). These polymers are different from those defined in Porssa et al and claimed in the present claims by virtue of the requirement that the polymer of the present claims have pendent cationic and zwitterionic groups and be crosslinked via incorporation of crosslinking monomers copolymerizable with other monomer components. The differences between the polymers of Porssa et al and Sahatjian et al would give no guidance to a person skilled in the art that the teachings could be combined.

Again, primarily because the target for the actives delivered in Porssa et al and Sahatjian et al are so different from one another, there would be no motivation for a person skilled in the art to consider use of any of the actives in Sahatjian et al in place of the anionic mucopolysaccharides in Porssa et al for delivery to the circulation. Therefore it would not have been obvious to replace the anionic mucopolysaccharides by a nucleic acid or a protein active of the types disclosed in Sahatjian et al.

For the above reasons, Applicants submit that the present claims are not obvious over Porssa et al in view of WO '575 and Sahatjian et al.

Reconsideration and withdrawal of the §103(a) rejection based on Porssa et al in view of WO '575 and Sahatjian et al are respectfully requested.

At pages 4 and 5 of the Action, Claims 60-69, 73-83 and 85-90 have been provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-84 of co-pending U.S. Application No. 10/842,461 in view of WO '575 and Sahatjian et al.

Applicants submit that the claims of copending Application No. 10/842,416 (the '416 Application) do not render obvious the presently claimed subject matter, and respectfully submit that the provisional double patenting rejection should be withdrawn.

The present claims recite that the cross-linked water-swellable polymer matrix comprises a polymer having pendant zwitterionic groups and pendant cationic groups. The claims of the '416 Application do not recite or render obvious a polymer having pendant zwitterionic groups and pendant cationic groups used in an implant loaded with pharmaceutical active, as the present claims recite. Therefore, Applicants respectfully submit that claims of the '416 Application are not a proper basis for a double patenting rejection of the present claims.

Reconsideration and withdrawal of this provisional double patenting rejection are respectfully requested.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: February 15, 2008